BROOKHAVEN NATIONAL LABORATORY GENERAL CLINICAL RESEARCH CENTER POLICY	NUMBER: IC-2.2	PAGE 1 OF 3
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SUBJECT: Intravenous Admixtures	REVIEWED BY: W. Gunther	GCRC Manager
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1.0 DEFINITIONS

Large Volume Parenteral (LVP) - A sterile solution of 100 ml or more, intended for injection and used in the diagnosis, cure, mitigation or treatment of disease or modification of physiological functions in humans, but excluding blood.

Intravenous Admixture (IA) - An LVP to which one or more additional drugs or solutions have been added.

2.0 PERSONNEL REQUIREMENTS/RESPONSIBILITIES

2.1 The preparation of sterile IAs requires a comprehensive knowledge of sterile techniques. Personnel must be familiar with the facility, equipment and techniques required to prepare an IA. Physicians, nurses (RN) and pharmacists are, by virtue of their educations and licenses, considered qualified. Other researchers may be qualified by the Responsible or Participating Physician after a briefing to both this document and the Dept. Infection Control Guideline IC-2, "Pharmacy" also, follow Guideline IC- 9.0, “Sterility and Pyrogenicity Testing”.

NOTE: Record of a researcher's qualification to perform this task shall be maintained both by the Dept. Training Coordinator and in the individual's GCRC staff file (clinical competency forms). GCRC staff are deemed “authorized personnel” if they have been determined competent to perform this clinical task.

2.2 IAs are prepared in the additive room (room 5-2B) in the laminar air flow hood or in the satellite facility’s hood. All must be certified. The final product is checked by the physician supervising the study. The nurse/technical staff shows used or partly used additives and explains the procedure of mixing to the physician. Only after this consultation may the IA be administered to the subject.

2.3 If consultation regarding mixing intravenous additives fluid is needed, contact the GCRC pharmacist.

3.0 ORDERING INTRAVENOUS ADMIXTURES

IAs must be ordered by the Physician. All orders must be written on the BNL prescription form (BNL F3113), one form for each subject. Physicians must specify the rate over which the infusion should run. .See Dept. Guideline, CRC POLICY 8.2, “Procurement, Dispensing and Disposal of Pharmaceutical”.

4.0 PREPARATION OF INTRAVENOUS ADMIXTURES

5.1 Upon receipt the physician/nurse/researcher interprets the order, checks the dosage, checks for compatibility and infusion rate.

NOTE: No call orders are accepted except to a nurse. Intravenous orders must be renewed every 24 hours in a complete form.

5.2 LVP are obtained from outside suppliers or from BNL stock supplies. Once the products have been received and inspected, they are stored in the pharmacy. (See also Dept. Guideline, CRC POLICY 8.1 “Central Pharmacy Access”.

NOTE: If pyrogen and sterility testing must be performed contact the Infection Control Practitioner.

5.3 Procedures

The preparer shall assure:

a) the compatibility of additives and that the resultant IA will be physically compatible and stable throughout the administration period. Discuss suitable alternatives with the prescribing physician when incompatibility problems occur.

NOTE: Assessment of chemical and/or physical compatibility is made by consulting the parenteral drug information guide. Problems in compatibility or stability arising from an order shall be directed immediately to the prescribing physician.

b) drug additives are appropriately diluted in the intravenous solution to assure complete solubility and minimize chemical irritation to the vein.

NOTE: In order to operate an efficient IA preparation system, as many additives as possible are mass reconstituted prior to preparation. Commonly used additives that are stable for extended periods under specified conditions are mass reconstituted.

Only one reconstitution program shall be in operation at a time.

c) the administration rate to be used is appropriate for the specific drug concentration to avoid unnecessary reactions.
d) the final product is pharmaceutically correct.
e) that fingernails are short and clean. Hands have to be washed with soap and water or scrubbed periodically with Alcare or similar product (foamed alcohol skin sanitizer).
f) that aseptic/sterile technique is used throughout the IA procedure. Particular care must be taken to avoid touch contamination and to keep the intravenous solution free from airborne contaminants.
g) that all LVPs are prepared in a certified laminar flow hood following the procedures in section 7.0, below. Additional compounds may be administered at the bedside in the IV line only, followed by a flush.
h) that rubber septa of vials and ampoule necks are swabbed with 70% sterile isopropyl alcohol. When transferring from ampoules filter needles shall be used to prevent contamination of the IA with glass particles. During the procedures extreme care must be exercised to avoid touch contamination of sterile objects.
i) that quality control checks described below (section 6.5) are performed for each IA prepared. The preparer must sign each prescription form in the section "RN noted".

NOTE: If a solution is prepared by a researcher the prescription form must be countersigned by the Responsible or Participating Physician.

5.0 LABELING AND CHECK

6.1 Immediately after the IA is completed the label is prepared. The label is affixed, in inverted position, over the manufacturer's label, in a position below the name of the intravenous solution.

6.2 Labels shall be marked with a 24 hour expiration date, except in the case of drugs which are stable for a shorter period of time or as noted in 5.3 g), in which case it will be so labeled.

6.3 All IAs shall be labeled with red labels (medication added). Each label shall include:

a) Subject's name
b) Additives: name and amount
c) Stability period (i.e., expiration date/time)
d) Administration Rate in ml/hr and drops/min
e) Initials of preparer
f) Warning labels, if applicable

6.4 The name and the amount of solution is printed on the plastic bag; do not cover it with the label.

6.5 The preparer performs the following checking operations:

a) The original order is checked against the label on the IA for accuracy and completeness of the subject's identity, identity of drugs, amounts added, solution used, infusion rate, volume of solution and expiration date/time.
b) The order is checked against the additives and amounts actually used.
c) The completed IA is visually inspected against light and dark backgrounds for particulate matter. If there is any evidence of foreign particles, clouding or precipitate, the IA is discarded.
d) The physician, after consultation with the preparer, approves the IA and it is then ready to be used.

NOTE: If there is any doubt that a sterile product may have been contaminated, discard the product and start over.

7.0 LAMINAR FLOW HOOD

NOTE: Dept. Laminar Flow Hoods are certified per Dept. Guideline and IC Guideline IC-02/3

a) Each user is responsible for the cleanliness of the hood
b) Only one type of intravenous solution should be prepared at a time in the hood.
c) The high efficiency particulate air (HEPA) filter keeps 99.99% of all particles 0.3 microns and larger from entering the work area which provides a dust- and bacteria-free atmosphere. Thus, if contaminants are not introduced into the hood by equipment or personnel, an extremely clean but not sterile environment exists.
d) The work area of the hood shall be wiped off with sterile isopropyl 70% alcohol a half hour before and after work is performed. This includes the walls and the accessories kept in the hood. The alcohol must evaporate prior to working.
e) The blower shall be turned on and allowed to run for at least 30 minutes before use. The hood should be turned off at 4:00 p.m. The front opening shall be covered with a vinyl cover or hood door when not in use.
f) The airflow shall be checked. The magnehelic pressure gauge should read between 0.5-0.75. If in excess of 1.25, the HEPA filter is overdue for replacement and shall be reported to the Building Manager.

g) All work in the hood shall be performed minimum six inches back from the front edge of the hood.
h) Objects that must be stored in the hood shall be kept along the side of the work surface area.
i) All equipment and supplies shall be cleaned and arranged well inside the hood. The IA procedure should be planned so that once it is begun, there will be no need to remove the hands from under the hood. In addition, unnecessary movements of the hands or supplies, and the placement of non-sterile objects between sterile objects and the airflow grating should be avoided.
j) The U.V. light is kept on overnight.
k) Each user is responsible for clean-up after use.
l) Microbial monitoring is not necessary.